

Other Formats: Citation MEDLINE

Links: Related Articles

☐ Order this document*J Clin Oncol* 1997 Jun;15(6):2403-13

Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial.

Burris HA 3rd, Moore MJ, Andersen J, Green MR, Rothenberg ML, Modiano MR, Cripps MC, Portenoy RK, Storniolo AM, Tarassoff P, Nelson R, Dorr FA, Stephens CD, Von Hoff DD

Institute for Drug Development, Cancer Therapy and Research Center, San Antonio, TX 78245, USA.

PURPOSE: Most patients with advanced pancreas cancer experience pain and must limit their daily activities because of tumor-related symptoms. To date, no treatment has had a significant impact on the disease. In early studies with gemcitabine, patients with pancreas cancer experienced an improvement in disease-related symptoms. Based on those findings, a definitive trial was performed to assess the effectiveness of gemcitabine in patients with newly diagnosed advanced pancreas cancer. **PATIENTS AND METHODS:** One hundred twenty-six patients with advanced symptomatic pancreas cancer completed a lead-in period to characterize and stabilize pain and were randomized to receive either gemcitabine 1,000 mg/m² weekly x 7 followed by 1 week of rest, then weekly x 3 every 4 weeks thereafter (63 patients), or to fluorouracil (5-FU) 600 mg/m² once weekly (63 patients). The primary efficacy measure was clinical benefit response, which was a composite of measurements of pain (analgesic consumption and pain intensity), Karnofsky performance status, and weight. Clinical benefit required a sustained (≥ 4 weeks) improvement in at least one parameter without worsening in any others. Other measures of efficacy included response rate, time to progressive disease, and survival. **RESULTS:** Clinical benefit response was experienced by 23.8% of gemcitabine-treated patients compared with 4.8% of 5-FU-treated patients ($P = .0022$). The median survival durations were 5.65 and 4.41 months for gemcitabine-treated and 5-FU-treated patients, respectively ($P = .0025$). The survival rate at 12 months was 18% for gemcitabine patients and 2% for 5-FU patients. Treatment was well tolerated. **CONCLUSION:** This study demonstrates that gemcitabine is more effective than 5-FU in alleviation of some disease-related symptoms in patients with advanced, symptomatic pancreas cancer. Gemcitabine also confers a modest survival advantage over treatment with 5-FU.

Publication Types:

- Clinical trial
- Multicenter study
- Randomized controlled trial